

## What the High-level meeting should prioritise when engaging the pharmaceutical industry on combatting AMR

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Antimicrobial resistance (AMR) is a global multisectoral challenge and there can be no sustainable resolution without an active involvement of the pharmaceutical companies. Therefore, as national level delegates come together for the High-Level Meeting (HLM) on AMR at UNGA in September 2024 they must utilise their position both as funders of innovation and access, and as customers or procurers of antimicrobials from these companies, to emphasise on their roles and responsibilities for tackling AMR across the following 5 themes:

- 1. Access: The lack of access and inadequate access to the right treatment as drivers of antimicrobial resistance stands well established. The Access to Medicine Foundation's 2021 AMR Benchmark and subsequent Appropriate Access Research Study highlight the enormous opportunity for leading manufacturers of antimicrobial products to tackle AMR by increasing the quality and reach of their access strategies. Companies have several options to increase access to essential antibiotics, antifungals, diagnostics and vaccines, including registration, technology transfers, voluntary licensing and local manufacturing so that more people and countries benefit. The September political declaration must encourage and mandate early and broader access planning by pharmaceutical companies both for existing as well as novel products. Governments can accelerate company efforts by providing strong and clear feedback on local demand and by investing in regulatory harmonisation schemes to make it easier, faster and cheaper for pharmaceutical companies to file for registration within multiple countries at the same time.
- 2. Stewardship: The overuse and misuse of antibiotics is another leading cause of antimicrobial resistance. The Access to Medicine Foundation's <u>Appropriate Access Research Study</u> highlights the opportunity for pharmaceutical companies to check this through stronger stewardship practices including responsible promotion and sales practices such as delinking of financial incentives from sales volumes. To support pharmaceutical companies to achieve this, the September political declaration must emphasise the need for more countries to invest in pull incentives like upfront market entry payment or a subscription-style model following England's National Health System (NHS) to ensure a viable market for pharmaceutical companies developing new products. Furthermore, the HLM must mandate the incorporation of the appropriate use and stewardship guidelines as part of all national treatment guidelines and ensure that WHO's Model List of Essential Medicines and AWaRe classification are used appropriately.
- 3. Supply: Pharmaceutical companies, specifically large R&D-based companies, have a central role in ensuring a continuous supply of high-quality medicines to support adherence, check resistance and prevent substandard and falsified products from entering markets. The HLM must call for an increased role by these companies to ensure a continuous supply of high-quality products including through their



support for local manufacturing initiatives. Governments can catalyse this further by making security of supply an important criterium in national and pooled procurement processes on top of the lowest price in tenders.

- 4. R&D: While antimicrobial resistance is growing at an alarming scale the same cannot be said for the R&D pipeline of antimicrobial products. The Access to Medicine Foundation's R&D report on biotechs highlights that biotechs account for 75% of all late-stage antibacterial R&D projects today, yet with many of the large research-based companies leaving antimicrobial R&D, these biotechs are struggling to secure the financing and resources needed to develop and commercialise these much-needed medicines. The unwavering priority is for the large R&D companies with the knowledge and the resources to deepen their investment and engagement in antibacterial and antifungal R&D with a focus on pathogens in the highest threat categories, and to further tailor the detail and specificity of stewardship and access plans. While push and pull incentives from governments and funder organisations is critical to address this R&D challenge for antimicrobials, it is critical for the large pharmaceutical companies to stay engaged in this space. The September political declaration must emphasise that better financing and support from large pharmaceutical companies beyond their investment in the AMR Action Fund is required and must be accelerated.
- 5. Responsible Manufacturing: Pollution caused by the release of antibiotic manufacturing waste into the environment is being increasingly recognised as one of the leading drivers of AMR. In the absence of a global regulatory landscape, the onus of checking the spread of AMR through manufacturing practices lies largely with pharmaceutical companies not just at their own manufacturing sites but across the entire supply chain. The Access to Medicine Foundation's Responsible Manufacturing Report highlights the huge gap that continues to exist in wastewater management practices of these companies and calls for increased transparency and accountability. There is a need for the September political declaration to call on the pharmaceutical industry to increase the uptake of responsible manufacturing practices. Already since the 2016 political declaration considerable progress has been noted catalysed by procurement decisions of some countries. In addition to calling for accountability and transparency, governments specifically in LMICs which house a large number of suppliers for active pharmaceutical ingredients (APIs) and related antibacterial products must explore the possibility of public-private partnerships (PPPs) to support the smaller yet critical players when it comes to ensuring responsible manufacturing across the entire supply chain.